

K113082

MAR - 8 2012

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92

Submitter Information:

Peridot Technologies NY Inc.
9131 Queens Blvd. Suite U,
Elmhurst, NY 11373

Date Summary Prepared:

September 1, 2011

Contact Person:

Omar Barlas
(Managing Director)
Peridot Technologies NY Inc.
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~~FDA/CDRH/DCC~~

~~OCT 18 2011~~

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Device Name and Classifications:

Trade Name(s):	Sonovision
Version:	2.0
Common Name:	Workstation software for ultrasound image acquisition, review, reporting and archiving.
Classification Name:	Image Processing System
Product Type:	Software Application
Device Classification:	892.2050
Product Code:	LLZ

Intended Use:

Sonovision is a software application intended for capturing, viewing, archiving and management of images and study data, acquired from Ultrasound machine and other similar medical imaging systems, when installed on suitable commercial standard hardware.

Sonovision is intended for use by obstetricians, gynecologists, radiologists, ultrasound technicians and cardiologists. The system is designed for use in hospitals, medical imaging labs and medical offices.

Substantial Equivalence:

Manufacturer	Device Name	510(k) Number	Clearance Date
AS Software Inc.	AS-OBGYN Information System	K051639	Aug 02, 2005
Ashva Technologies Pvt. Ltd.	iMagic v2.0	K071602	Jul 23, 2007

Device Description:

Sonovision is an Ultrasound Imaging Solution/Ultrasound Workstation Software for images Acquisition, Study Management & Reporting.

Sonovision capture's images and video clips from Ultrasound machine and save uncompressed images along with patient information to local database.

- Saving, searching and loading Studies into secure local Database
- Save Studies as DICOM File, Image Files(JPG, J2K, TIFF and PNG) & Ultrasound Reports
- Send or Retrieve Studies to PACS Server over the network
- Make DICOM CD or DICOM DVD
- Use computer printer to print ultrasound images
- Image Zooming, Panning, Flipping, Rotating Options
- Add Text Annotations on Images
- Record Video Clips and covert them into DICOM Series/frames

Sonovision does NOT use lossy (irreversible) compression during image handling, manipulation or storage in local Database (It creates uncompressed TIFF Files). However when user converts images or series to DICOM or other Image formats(like JPG, PNG) manually then it may apply lossy (irreversible) compression on images.

All hardware used by Sonovision 2.0 (Including computer, storage drives, network interfaces, video capture cards, monitors and printers) are commercial off-the-shelf equipment

Comparison to Predicated Devices:

Sonovision is substantially equivalent to the following legally marketed devices:

Specification	Sonovision	AS-OBGYN	iMagic v2.0
Image Capturing	YES	YES	YES
Video Capturing	YES	NO	NO
DICOM Conversion	YES	YES	NO
Integration with PACS	YES	YES	NO
Make DICOM CD/DVD	YES	NO	YES
Lossy/Lossless Compression	Lossless (Uncompressed)	Lossy (Compressed)	Lossy (Compressed)
Image Review	Zoom/Pan/Flip/Rotate Brightness/Contrast/Text Annotations	Zoom/Pan	Zoom/Pan/Flip/Rotate Brightness/Contrast
Reporting	YES	YES	YES



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - W066-G609
Silver Spring, MD 20993-0002

Mr. Omar Barlas
Managing Director
Peridot Technologies NY Inc.
9131 Queens Blvd. Suite U
ELMHURST NY 11373

MAR - 8 2012

Re: K113082

Trade/Device Name: Sonovision v2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 23, 2012
Received: February 23, 2012

Dear Mr. Barlas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

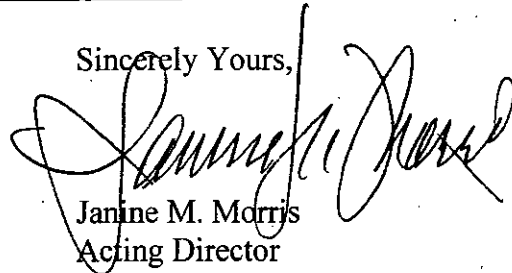
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director

Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113082

Device Name: Sonovision v2.0

Indications for Use:

Sonovision is intended for use by obstetricians, gynecologists, radiologists, ultrasound technicians and cardiologists. The system is designed for use in hospitals, medical imaging labs and medical offices.

Sonovision works as Workstation Software for Ultrasound Image Acquisition, Reviewing, Patient studies data management, Reporting, Sending Studies to PACS Server or Making DICOM CD/DVD.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Prescription Use ☒ AND/OR Over-The-Counter Use ☐
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

K113082 Mary Spetal
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113082